K102134
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510(K) SUMMARY

DEC 23 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter's Name: United Integrated Services Co., Ltd.

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Contact: Mr. David O. Chang / Vice President

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Prepare Date : May 24,2010

2. Device Name:

Trade Name: Multi-Channel Laser Therapy System,
Model no.: LA-1200

Common Name: Laser Therapy

Classification name lamp, infrared, therapeutic heating

3. DEVICE CLASS The Multi-Channel Laser Therapy System, **(Model no.: LA-1200)** has been classified as
Regulatory Class: II
Product Code: ILY
Regulation Number: 21CFR 890.5550

4. Predicate Device: The predicate device is the **Multi-Channel Laser Therapy System, MODEL LA-400 (K082686)** marketed by **United Integrated Services Co., Ltd.**

5. Intended Use: The **Multi-Channel Laser Therapy System (Model no.: LA-1200)** is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and the joint pain and stiffness, for the temporary relief of minor joint pain associated with arthritis, for the temporary increase in local circulation where applied and the relaxation of muscles.

6. Device Description: The Multi-Channel Laser Therapy System LA-1200 is a non-invasive, portable therapeutic medical laser designed to deliver light energy to the target tissue. It is intended to emit energy in the infrared spectrum for the purpose of temporary relief of minor muscle and the joint pain associated with arthritis, for the temporary increase in local circulation where applied and the relaxation of muscles.

LA-1200 is the low level laser of two wave bands. One is 660nm (red light, visibility) and the other is 808nm (infrared light, invisibility).

LA-1200 contains twelve (12) channels of laser. For each channel of the Multi-Channel Laser Therapy System, LA-1200 makes use of cup + laser diode assembly hand-held to deliver the light energy to the designated treatment areas. The cup + laser diode assembly are put on the skin for treatment.

Note A : Basic operation and treatment of LA-1200 is utilizing the laser module mounted in the cup (we call **laser module cup**) which will be hand-held and put on skin easily.

7. Performance Summary:

In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included ISO 13485, IEC 60825-1, IEC 60601-1 and IEC 60601-1-2 requirements.

As shown from the Appendix 11-8 to Appendix 11-13, the bench testing was also performed to demonstrate that the Multi-Channel Laser Therapy System (Model no.: LA-1200) increases the temperature of the skin exposed to the laser module cup and maintains a skin temperature of 40 ~ 45℃ (104 ~ 113℉) following 15 minutes exposure to the light.

8. Conclusions:

The **Multi-Channel Laser Therapy System (Model no.: LA-1200)** has the same intended use and similar technological characteristics as the **Multi-Channel Laser Therapy System, MODEL LA-400 (K082686)** marketed by **United Integrated Services Co., Ltd.** Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **Multi-Channel Laser Therapy System (Model no.: LA-1200)** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
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United Integrated Services Corporation Ltd.
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Taipei Hsien, Taiwan, R.O.C.
23144

DEC 2 3 2010

Re: K102134
Trade/Device Name: Multi-Channel Laser Therapy System
Model no.: LA-1200
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: December 14, 2010
Received: December 17, 2010

Dear Mr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEC 2 3 2010

Indications for Use

510(k) Number (if known): K102134

Device Name: Multi-Channel Laser Therapy System
Model no.: LA-1200
United Integrated Services Co. Ltd.

Indications for Use:

The Multi-Channel Laser Therapy System (Model no.: LA-1200) is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and the joint pain and stiffness, for the temporary relief of minor joint pain associated with arthritis, for the temporary increase in local circulation where applied and the relaxation of muscles.

Prescription Use V AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102134